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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,878	03/15/2001	James H. Pickar	AM100226	5270
26646	7590	02/24/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/808,878
Filing Date: March 15, 2001
Appellant(s): PICKAR, JAMES H.

Thomas J. Meloro
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 14 appealing from the Office action mailed September 10, 2003.

(1) (1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

US Patent Re. 36,247 Plunkett et al. July 6, 1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 7, 11, 12 and 69 are rejected under 35 U.S.C. 103(a) over Plunkett d al.

These rejections are fully set forth in prior office action mailed September 10, 2003, and reiterated in full below.

(10) Response to Argument

Claims 7, 11, 12 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plunkett d al. (USPN RE 36,247).

Plunkett et al. (USPN RE 36,247) teaches a method of treating hot flashes comprising administering continuously and uninterruptedly both progestogen and estrogen in daily dosage units, see claims 21-34, col. 3, lines 51-59 and col. 8 lines 62-64 in particular. Plunkett d al. (USPN RE 36,247) also teaches conjugated equine estrogen/medroxyprogesterone as one of the estrogen/progestogen combinations useful in its method, see claims 21-34. Plunkett teaches the minimum and maximum dosages for medroxyprogesterone (MPA) and conjugated equine estrogens (CEE) to be 1 mg/day and 15 mg/day, and 0.300 mg/day and 2.5 mg/day, respectively, and the preferred dosages are 1-2.5 gm (MPA) and 0.300-0.600 mg (ECC) respectively, see claims 34-35, see also Table IA, col. 4, in particular.

Plunkett et al. does not particularly teach the dosages of conjugated equine estrogen/medroxyprogesterone claimed herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ conjugated equine estrogen/medroxyprogesterone in the specific dosages

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claimed herein in a method of treating hot flashes.

One of ordinary skill in the art would have been motivated to employ conjugated equine estrogen/medroxyprogesterone in the specific dosages claimed herein in a method of treating hot flashes because they (dosages herein) fall within the therapeutic ranges of the conjugated equine estrogen/medroxyprogesterone taught by the prior art. Optimization of amounts is within the purview of the Skilled Artisan, and is therefore obvious absent evidence to the contrary. No such evidence is seen.

Appellants' arguments have been fully considered but they are not persuasive.

A prima facie case of obviousness has been established. Appellants first argue that prima facie case of obviousness has not been established. Particularly, appellants argue "there is nothing in Plunkett to teach or suggest the selection of 1.5 mg MPA for the treatment of vasomotor symptoms in combination with about 0.3 to about 0.45 mg CEE." Note that Plunkett teaches that MPA can be employed at minimum dosage of 1.0 mg and maximum dosage of 15 mg, and preferred range of 1-2.5 mg/day (claim 32). Note that the claimed dosage herein, 1.5 mg/day, fails within the preferred range. Note also that the claimed dosage herein, 0.3-0.45 mg of CEE, falls within the dosage range of 0.300-0.600 mg disclosed by Plunkett. It would have been prima facie obvious to one of ordinary skill in the art to use 1.5 mg/day of MPA and 0.3-0.45 mg/day of CEE because the amounts herein are within the relatively narrow range disclosed in the prior art.

The objective evidences on the record are not sufficient to overcome the obviousness.

Appellant draws the examiner's attention to data presented in the specification showing the efficacy of the dosages herein versus that of the "common daily dosages" of Premarin and MPA.

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Note that in order to overcome obviousness appellant must demonstrate unexpected and significant results in comparison with the closest prior art, i.e., Plunkett. No such comparative data has been provided. Appellants state that the closest example in Plunkett is a regimen comprising 0.600 mg CEE and 2.5 mg MPA. The specification on page 9 provides a comparative example between 60.625 mg of CEE, and not 0.600 mg of CEE. Furthermore, the data presented does not constitute unexpected results because according to appellants' remarks, the data shows similar efficacy of the following regimens: 0.625 CEE/2.5 MPA, 0.45 CEE/1.5 mg MPA, 0.30 CEE/1.5 MPA. Some data points are overlapping in both number and severity of hot flushes. Assuming arguendo that lower dose of MPA and CEE claimed herein yield similar therapeutical results, then the teachings of the prior art is confirmed. Plunkett teaches a wide range of CEE/MPA as effective in treating hot flushes. Therefore, the showing on page 9 of the specification indeed confirms the teachings of the prior art that the entire range disclosed in Plunkett is effective in treating hot flushes.

The two declarations of Dr. Lobo submitted under 37 CFR 1.132 have been fully considered, but are not persuasive to remove the obvious rejection herein. Dr. Lobo asserts that conventional accepted combination treatment of conjugated equine estrogen/medroxyprogesterone is 0.625 mg/2.5 mg daily, and such amounts have been accepted as the minimum effective amounts. Therefore, the lower dosage (0.3 to 0.54 mg/1.5 mg) as claimed in the application would have not been expected to be effective in view of the conventional accepted dosage.

The assertion is not persuasive. Note the Plunkett et al., a patent issued in the past 20 years contradicts this very proposition since it teaches ranges of CEE/MPA that encompass the

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dosage claimed herein, with 0.6 mg/2.5 mg as the up limit of the preferred embodiments. The claimed amounts are within the range disclosed in the prior art. It is noted that the range are relatively narrow, and what appellants proved is nothing more than what is expected according the cited prior art. As to the alleged unexpected additive or synergistic effect of MPA and CEE, it is noted that Plunkett et al. particularly teach the combination of MPA/CEE. Further, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). For the above reasons, it is believed that the rejections should be sustained.


(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

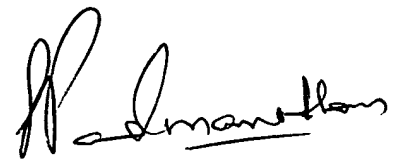
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